K063447

ATTACHMENT 4

AUG 16 2007

Insight Discovery

510(k) Summary

Submitted by:

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Submitted on: April 13, 2007

Section 1: Device Name

Proprietary Model Name:	Insight Discovery
Common or Usual Name:	Diagnostic Electromyograph
Regulatory Name:	Diagnostic Electromyograph
Regulation Number:	21 CFR 890.1375
Product Code:	IKN
Regulatory Class:	II

Section 2: Indications for Use

- To measure bilateral differences in surface EMG along the spine
- To measure surface EMG along the spine during functional tasks
- To measure bilateral differences in skin temperature along the spine
- To measure Range of Motion of the three spinal regions
- To measure patient self-reported pressure sensitivity in joints and muscles
- To measure Heart Rate
- To chart patient progress during the course of treatment

Section 3: Device Description

The Insight Discovery is a non-invasive, multi-modality physiologic monitoring device. The Insight Discovery contains the following six sensor types: (1) surface EMG used to measure muscle activity, (2) infrared temperature sensor used to measure skin temperature, (3) algometer used to measure patient self-reported pressure sensitivity, and (4) heart rate sensor to measure heart rate, (5) an inclinometer used to measure end-point range of motion, and (6) a wireless version of the inclinometer.

Hardware

The Insight Discovery hardware consists of an instrument console and six different sensor types. The sensor types plug directly into the front panel of the Insight Instrument Console, with the exception of the wireless inclinometer. The Insight Discovery Instrument Console is powered via a UL2601 listed power supply. The Instrument Console is connected to a personal computer (IBM compatible) via an isolated USB port connection.

Software

The Insight Discovery software displays real-time surface EMG, spinal Range of Motion, skin temperature, pressure, and heart rate readings, allowing the user to ensure that readings are stable prior to data collection. The Insight Discovery software allows the user to: (1) enter patient information, (2) record surface EMG, spinal Range of Motion, skin temperature, pressure and heart rate readings, (3) graph surface EMG, spinal Range of Motion, skin temperature, pressure and heart rate readings, and (4) print out reports, including an integrated report containing the results of all five recording types.

Section 4: Predicate Device

This section documents the substantial equivalence of the Insight Discovery to a legally marketed device. Specifically, this section documents the substantial equivalence of Insight Discovery to the following product:

Manufacturer	Predicate Device Name	510(k) Number
Insight Millennium III	Fasstech	K023209

The Insight Discovery is equivalent to this legally marketed device in the following ways:

- The physical characteristics and electrical characteristics (performance characteristics) of the Insight Discovery are identical as to the Insight Millennium III, as cleared by FDA. The only difference is the addition of an optional wireless dual inclinometer in the place of the standard wired inclinometer.

The Insight Discovery differs from the legally marketed device in the following ways:

- The addition of an optional wireless dual inclinometer
- The extension of the Insight software to interface with the new inclinometer

Predicate Device Comparison Chart

Feature	**Insight Discovery**	Insight Millennium III
Four Channels of surface EMG	**Yes**	Yes
Skin Temperature measurement via infrared thermal scanner	**Yes**	Yes
Range of Motion Sensor	**Yes**	Yes
Algometer	**Yes**	Yes
UL-2601 listed power supply	**Yes**	Yes
Heart-rate measure using IR Phethsmograph	**Yes**	Yes
Wireless version of the inclinometer	**Yes**	N/A

Section 5: Performance Specification

The Insight Discovery specifications are summarized below and are identical to Insight Millennium III (except for the addition of the Dual Inclinometer):

EMG

Electrodes:	4 ea. Smart Sensors with low-noise preamplifiers integral to electrode assemblies
Calibrated Range:	0.1 – 999 uV
Input Bias Current:	Less than 2.0 Picoamperes
Differential Input Impedance:	Greater than 1,000,000 Megaohms
Common Mode Rejection:	150 dB
Bandwidth:	20-500 Hz (50/60 Hz notch)
Noise:	Less than 0.1 uV (inputs shorted)
Detector:	Log power detector, 250 mS averaging filter.
Controls:	None

Temperature

Calibrated Range:	55°F - 120°F
Accuracy:	$\pm$0.2°F nominal
Sensors:	Two thermopile, fixed 2.5" apart (center-to-center)
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 0.5" ABS Plastic Outer Ring.
Size:	5.5"L x 3.5"W x 2.5"H. Weight 15 oz.

Algometer

Calibrated Range:	0-100 lbs.
Accuracy:	$\pm$3% nominal
Contact Area:	1.0 cm^2
Sensor:	One pressure transducer attached to a stiff rod.
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 3.0" ABS Plastic Stiff Rod.
Size:	5.5"L x 1.75"W x 2.5"H. Weight 9 oz.

Heart Rate Sensor

Sensor Type	IR Plethsmograph (attached to finger with Velcro)
Output Voltage:	5 – 50 mV, typical at rest
Output Impedance:	1 kΩ, nominal
Weight:	28 grams
Sensor Size:	15 x 15 x6.3 mm

Single Inclinometer

Range:	360 degrees
Accuracy:	+/- 1 degree nominal
Axes:	One
Controls:	Enter and Skip Buttons

	Physical:	Case Material: Impact resistant, flame retardant ABS. 3.4"H x 3.5"W x 1.25"D. Weight 6.5 oz.
Dual Inclinometer		
	Range:	360 degrees
	Accuracy:	+/- 1 degree nominal
	Axes:	Three
	Controls:	None
	Bluetooth Type:	Class 1 / +7dBm 5 mW
	Physical:	Case Material: Impact resistant, flame retardant ABS. (1) 3.9"L x 2.0"W x 0.8"D. Weight 2.9 oz. (2) 1.4"L x 1.4"W x 0.6"D. Weight 1.8 oz.
Instrument Console		
	Inputs:	4 each EMG electrodes 1 each inclinometer 1 each temperature sensor 1 each algometer sensor 1 each Heart Rate sensor
	Output:	Isolated USB
	A/D converter:	16 bit, 16 channel
	Controls:	None
	Power:	12V, 500 mA UL-2601 listed power supply.
	Physical:	Case Material: Impact resistant, flame retardant ABS. 3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz.

Section 6: Patient Safety

The Insight Discovery patient isolation is assured by the following two electrical isolation barriers:

1. Medical-Grade Universal Power Supply: This device is a UL2601 compliant AC line to 12 VDC, 28 W converter. This internal power supply is partitioned from all other circuitry via an earthed steel chassis. The power supply accepts 85-264 VAC, and 47-63 Hz via a IEC 60320 fused input module.

   This supply provides low-level isolated power to the Non-Patient Side of the Insight Discovery circuitry, as well as power to the DC-to-DC isolation converter that powers to the Patient Side (see #2 below).

2. DC-to-DC Patient Isolation Converter: This converter is a UL2601 compliant DC-to-DC converter, and meets the dielectric withstand and leakage current requirements of the UL2601 standard for Patient Care Equipment with isolated patient leads.

   This converter supplies all power to patient-applied parts and related circuitry. Each of the direct patient-applied parts have individual current limiters for fault condition.

In addition, the Patient Side of the Insight Discovery is isolated from the host PC as follows:

3. Optically Isolated Data Link: Signals are converted from analog voltages to 16 bit digital values by the analog-to-digital converter (ADC). The digital data is sent to and from the USB of the PC across an optically isolated data link.

   This optical link is UL2601 compliant, providing the dielectric withstand and low leakage current characteristics specified in UL2601.

Section 7: Conclusion

The Insight Discovery is substantially equivalent to the predicate device. Furthermore, the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fasstech
% Intertek Testing Services NA, Inc.
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087
ATTN: Daniel W. Lehtonen

AUG 16 2007

Re: K063447
Trade/Device Name: Insight Discovery Diagnostic Electromyograph
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, HCC
Dated: August 2, 2007
Received: August 3, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Insight Discovery

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063447